

Appl. No. 10/590,431
Amendment dated: May 18, 2009
Reply to Office Action dated: November 19, 2008
Docket: 411044.00004

REMARKS/ARGUMENTS

In a non-final Office Action mailed November 19, 2008, the Examiner in charge of the above-identified application rejected Claims 1-14 as being unpatentable over Lee (US 3,761,408) in view of Carroll et al. (US 6,706,536).

Applicants respond by submitting the amendments above, and comments set forth hereinbelow. Based on this submission, reconsideration of the merits of this patent application is respectfully requested.

Declaration

Applicant acknowledges the Examiner's request for an amended Declaration. Applicant is in the process of obtaining the inventor's signature. A new Declaration will be submitted to the USPTO in due course.

Specification Amendments

The Abstract has been amended to comply with MPEP 608.01(b). No new matter has been added to the Abstract.

Claim Amendments

Claims 1 and 3-5 have currently been amended and new claims 15 and 16 have been added. Claims 1-16 are currently pending in the present application.

Claims 1 and 3-5 have been amended for the sake of improved clarity.

Support for the amendment made to claim 1 is provided, for example, at page 6, lines 1-5 and FIGS. 2A and 2B. Support for new claims 15 and 16 is provided, for example, at page 6, line 1. No new matter is added with the above-identified claim amendments and new claims. Reconsideration and allowance of the claims is respectfully requested.

Claim Rejections Under 35 U.S.C. § 103

Examiner has rejected claims 1 and 8-9 under 35 U.S.C. 103(a) as being unpatentable over Lee in view of Carroll *et al.*

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Without conceding to the correctness of the Examiner's rejection, the method defined by claim 1 has been amended to clarify that the sample of whole blood is collected *directly* into the container.

Lee discloses a method of separating whole blood by inserting a flexible membrane into a container, collecting blood within the flexible container, sealing the container, and centrifuging the container to cause plasma having a predetermined size to filter out through a portion of the membrane into the container, and retain cells having a greater relative size within the flexible membrane.

Lee does not, however, teach or suggest a method for separating whole blood, by a step of collecting a sample of whole blood from a subject *directly* into a container. In addition, the step of centrifuging in Lee does not result in the separation of the whole blood into distinct layers containing cells, gel and plasma. This is because in Lee the cells are retained within the flexible membrane and cannot form a distinct layer within the container.

Furthermore, as Carroll *et al.* does not teach or suggest the features in the steps of the presently claimed method, it cannot remedy the deficiencies of Lee. In Carroll, the container is oriented in the spectrophotometric device, so that the *second end* of the container is in closest relative juxtaposition with the cell layer. In contrast, the present invention, the cell layer is in closest relative juxtaposition with *first end* of the container. Also, the orientation of the container in the present invention permits measurement of the plasma layer using standard spectrophotometric devices. In Carroll, the orientation of the container requires the use of a movable, specialized sample holder. As a result, the presently claimed method is patentable in view of the cited references.

Removal of Examiner's rejections under 35 U.S.C. § 103 is respectfully requested in view of the foregoing amendments and comments.

Summary

It is respectfully submitted that the above-identified application is now in a condition for allowance and favorable reconsideration and prompt allowance of these claims are respectfully requested. Should the Examiner believe that anything further is desirable in order to place the application in better condition for allowance, the Examiner is invited to contact Applicants' undersigned attorney at the telephone number listed below.

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Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Fees

A petition for Extension of Time accompanies this response. Please charge the surcharge fee to Deposit Account 17-0055. No other fees are believed due; however, if any additional fees are due, in this or any subsequent response, please charge Deposit Account 17-0055.

Respectfully submitted,

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